acid.

DH

15. (Amended) The method of claim 14, wherein the nucleic acid is bound to a microparticle.

REMARKS

Discussion of Claim Amendments

The claims have been amended to more particularly point out and distinctly claim the subject invention. Claim 1 has been amended to delete objectionable and extraneous words. Claim 4 has been amended to make the antecedent basis for the term "contaminating nucleic acid" more clear. Claims 14 and 15 have been amended to remove a typographical error. Thus, no new matter has been added by way of the present Amendment.

Discussion of the Enablement Rejection

The Office Action alleges that claims 1, 4, 7, 8 and 12-16 are directed to subject matter not accompanied by an enabling disclosure in the specification. After applying the Forman factors to the claims, the Office Action specifically alleges that the claims are objectionable for failure to provide a distinction between a "first nucleic acid sample that is to be amplified and one attempting to amplify a second nucleic acid." This point of rejection is respectfully traversed.

Applicants respectfully note that claim 1, as pending, provides a contaminated nucleic acid analyzer (step (a)). The method does not recite that the analyzer is to be used for a subsequent analysis of a second nucleic acid, and therefore, the Office has rejected the claim. While use of the treated analyzer to analyze a second sample is a natural use of the treated

analyzer, applicants do not understand why additional steps need be recited when these steps are not essential to the novelty or non-obviousness of the present invention. Therefore, applicants request that this point of rejection be withdrawn.

The Office Action also specifically alleges that the current used to inactivate a first sample would either 1) also inactivate the second sample (whose presence is inferred by the Office), or 2) when the current is turned off the first nucleic acid would be released. Applicants wish to complement the Examiner for the thoroughness of his analysis, but still traverse the rejection.

Whether the current is reduced, modified, or "turned off" before the analysis of the second sample is immaterial to the enablement of the present invention. The Office has tried to infer the mode of action by which the invention must work, and having concluded that one mechanism by which the invention does work is be sequestering a nucleic acid driven to an electrode to prevent its amplification and detection in the second sample, reasons that the contamination treatment will either be ineffective or will prevent the amplification and detection of the second sample. However, applicants take no position as to "how" the invention works. Applicants merely have discovered that it does work. While in most embodiments applicants might advise turning off the current, this is not a known limitation of the process. Accordingly, applicants respectfully request withdrawal of this point of rejection.

Similarly, the Office Action rejects claim 12 which recites fragmentation of the nucleic acid, because the Office has rationally considered the potential effects of fragmenting contaminating nucleic acids in a nucleic acid analyzer and concluded that such fragmentation could exacerbate rather than attenuating the interference caused by a contaminate.

Applicants respectfully traverse the rejection. Applicants have performed experiments with the circuit disclosed in the specification, and have found that the fragmentation of contaminating nucleic acids does indeed attenuate the signal generated by the contaminates. Applicants are not required to explain the phenomena. Moreover, applicants respectfully point

out that the prima facie enablement rejection is not adequately made here because the Patent Office's theory (that fragmentation makes things worse) is unsupported by empirical evidence (i.e., experimentation) supporting the Office's theory. For both the foregoing reasons, applicants respectfully request withdrawal of the rejection.

Claim 14 is rejected because the Office is unconvinced that the (migratory) force applied to a nucleic acid to be eluted would be sufficient to separate the nucleic acid from the particle. In essence, the Office rejects claim 14 as encompassing a non-enabled embodiment. Applicants respectfully traverse.

While applicants are not aware of a set of conditions that comport with the speculation provided by the Office, applicants' are unaware of any such non-enabled conditions. More importantly, however, claim 14 recites that current "flows through the second liquid medium, such that (g) the nucleic acid is eluted... ." Thus, non-enabled embodiments are not claimed. Additionally, if the Office is correct in speculating that the particles could be made too small to allow any elution, the ordinarily skilled artisan could rely on the same general knowledge relied on by the Office to understand the source of the problem and avoid non-enabled embodiments without undue experimentation. Applicants therefore respectfully request withdrawal of the rejection.

Discussion of the Indefiniteness Rejections

Claim 1 stands rejected over the use of the term "waste portion" in step (d). This rejection is obviated by the amendment. The term "waste portion" was only present to indicate a useful embodiment of the present invention, however, applicants now realize that the term was misleading inasmuch as any portion of a first sample can be effectively treated by the method of the present invention.

Claim 4 stands rejected for alleged insufficient antecedent basis for the term "contaminating nucleic acid." Applicants agree that the claim appears to be more clear as amended and thank the Examiner for his diligence.

Claim 8 stood rejected for alleged insufficient antecedent basis for the limitation "first nucleic acid complex." The claim has been amended to provide clear antecedent basis.

Claim 14 stands rejected for failure to provide an antecedent basis for the term "particle." This rejection has been obviated by amendment.

Claim 8 also stands rejected as allegedly being confusing. Specifically, the Office Action points out that discarded waste is to be treated. Applicants point out that the waste portion is treated prior to discarding, and that the discarding step is not recited in the claim. Additionally, it should be noted that the waste can be stored in a waste receptacle and need not be discarded *per se*. Also, for clarification, it should be noted that a common source of PCR contamination is aerosols from the waste, which aerosols are derived from the waste portion of samples in prior art embodiments.

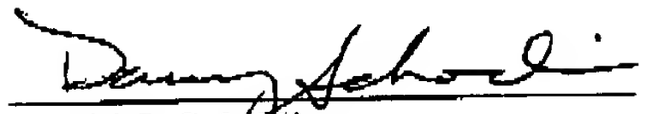
For all the foregoing reasons, applicants respectfully submit that the pending claims are now clear and definite.

Conclusion

The Examiner is respectfully requested to pass the subject application to allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to telephone applicant's undersigned representative.

09/492,213
6416.US.P1

Respectfully submitted,
G. Gundling, *et al.*



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G. Gundling, et al.

Application No.: 09/492,213

Filed: January 27, 2000

Title: A METHOD OF REDUCING CONTAMINATION IN AN ASSAY VESSEL

Case No.: 6416.US.P1

Group Art No.: 1634

Examiner: B. Sisson

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTACHMENT TO PRELIMINARY AMENDMENT

TRANSMITTED OCTOBER 8, 2002

Dear Sir:

Pursuant to 37 C.F.R. § 1.121, applicants provide herein marked-up copies of each claim that was pending prior to the entry of, and amended by way of, the Preliminary Amendment transmitted via facsimile on May 24, 2001.

AMENDMENTS

In the claims:

1. (Twice Amended) A method of [processing a sample to reduce] reducing contamination in a nucleic acid analyzer, the method comprising the steps of:

(a) providing a nucleic acid analyzer containing a first sample, wherein the first

sample comprises a first nucleic acid that could contaminate a PCR reaction to be performed on a second sample;

(b) contacting a first electrically conductive surface and a second electrically conductive surface to a portion of the first sample;

(c) applying a voltage between the first electrically conductive surface and the second electrically conductive surface[; and

(d) adjusting the voltage] to reduce the ability of the first nucleic acid [in the waste portion] of the first sample to be amplified or detected in a PCR reaction process involving the second sample.

4. (Twice Amended) A method of reducing contamination in a reaction vessel used for PCR, the method comprising the steps of:

(a) providing a reaction vessel containing a first sample, wherein the first sample contains a nucleic acid that could contaminate a PCR reaction to be performed on a second sample;

(b) locating a first electrode and a second electrode adjacent to the [contaminating] nucleic acid that could contaminate the PCR reaction, if present;

(c) applying a voltage between the first electrode and the second electrode; and

(d) adjusting the voltage to reduce an ability of the contaminating nucleic acid to be amplified or detected in a PCR reaction.

8. (Amended) The method of claim 7, further comprising the following steps after step (a) and before step (b):

(a1) contacting the first sample with a binding member so as to form two portions of the first sample consisting of

(i) an analytical portion comprising a first nucleic acid complex, wherein the first

nucleic acid complex comprises a bond between a portion of the first nucleic acid and the binding member, and

(ii) and a waste portion, wherein the waste portion is the portion of the first sample that is not bound to the binding member,

(a2) separating the waste portion of the first sample from the analytical portion, and

(a3) aspirating the waste portion of the first sample into the electrically conductive pipettor,

wherein in step (b) the portion of the first sample contacted by the first electrically conductive surface and the second electrically conductive surface is the waste portion of the first sample, and

wherein the reduction in the ability of the first nucleic acid to be amplified or detected in a PCR reaction process is effected by fragmenting the first nucleic acid in the waste portion of the first sample.

14. (Amended) A method of amplifying a nucleic acid, the method comprising:

(a) providing a nucleic acid in a first liquid medium,

(b) binding the nucleic acid to a solid support to form a bound nucleic acid,

(c) substantially separating the bound nucleic acid from the first liquid medium,

(d) mixing the bound (Particle) nucleic acid with a second liquid medium,

(e) positioning a portion of the bound nucleic acid and second liquid medium mixture between two electrodes,

(f) applying a voltage between the electrodes sufficient to cause a current to flow through the second liquid medium, such that

(g) the nucleic acid is eluted from the particle,

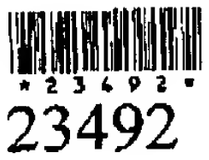
(h) adding amplification reagents to the eluted nucleic acid in the second liquid medium sufficient to amplify the nucleic acid thereby forming an amplification mixture, and

(i) maintaining the amplification mixture under suitable conditions to amplify the nucleic acid.

15. (Amended) The method of claim 14, wherein the nucleic acid is bound to [particle is] a microparticle.

Respectfully submitted,

G. Gundling, *et al.*



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